

REMARKS

Amendments to the Claims

Claims 1-49 have been cancelled.

Claims 50-66 have been added. The new claims introduced in the present response are supported by the original specification as described in the table bellow:

Claim No.	Page(s)	Line(s)
50	9	7-17
Step A	17; 18	28-32; 1-3
Step B	15; 16; 17	26-30; 1-5; 20-27
51	9; 10; 12; 13	18-27; 5-8; 26-31; 1-5
Step (i)	9; 10	28-30; 19-24
Step (ii)		
52	9-10	Line 28 to line 4; 19-24
53	9-10	Line 28 to line 4; 19-24
54	9; 10	Line 28 to line 4
55	9; 10, 21	Example 1
56	9; 10	21-23; 9-14; Example 2
57	10, 22	9-14, Example 3
58	16	5-17
59	16	5-17, Examples 16-20
60	16	5-17
61	16	5-17
62	16	5-6
63	16	5-17
64	18	10-17
65	18	10-17
66	18	25-30

RESTRICTION REQUIREMENT

The Examiner has required election in the present application between:

Group I, claim(s) 41, 48, drawn to a pharmaceutical composition.

Group II, claim(s) 49, drawn to a method for treating a neoplastic tumor.

Group III, claim(s) 28-33, 40, 45-46, and 47 (in part), drawn to a process for the preparation of sterile solutions of active pharmaceutical ingredients.

Group IV, claim(s) 1-2, 4-6, drawn to a process for the preparation of anhydrous active pharmaceutical ingredients comprising azeotropic distillation.

Group V, claim(s) 8-10, drawn to a process for the preparation of anhydrous active pharmaceutical ingredients comprising reaction in an anhydrous solvent and direct isolation in a pure and anhydrous form.

Group VI, claim(s) 11-16, drawn to a process for the preparation of anhydrous docetaxel comprising purification by chromatography.

Group VII, claim(s) 17-27, and 47 (in part), drawn to a process to effect the solubilization of docetaxel comprising inducing crystallization, isolation and drying of the crystals.

For the purpose of response to the restriction requirement, Applicants elect, with traverse, Group IV, claims 1-2, 4-6 and elect the compound I. New claims 51-59 are readable on the elected group of invention. Claims 50 and 60-66 are generic.

Applicants further elect the solvent species ethanol. Claim 55 recites this species of solvent. Claims 53 and 54 are generic or subgeneric with respect to the solvent used.

Applicants traverse the restriction requirement to the degree that, in their view, the examination should be conducted under an election of species procedure. That is, the invention relates to methods for making sterile preparations of the compounds of formulae (I) and (II) from such compounds in anhydrous form or forms with specified hydration content. The methods by which such forms of the compounds (I) and (II) represent patentably distinct species that should be examined in turn following election of species practice.

Accordingly, Applicants submit that the Groups III through VI should be rejoined, and that the presently elected method for obtaining anhydrous compounds of the formulae (I) or (II) of azeotropic distillation should be considered as a species of this process step. Should the Examiner agree, then Applicants would add claims related to the further species represented by Groups V and VI for later consideration in this application if it is determined that the elected species (Group IV) is found patentable.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell Reg. No. 36,623 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: July 30, 2008

Respectfully submitted,

By 

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Attachment: "Docetaxel" - Wikipedia Article